

IMPLEMENTATION OF THE RAPID CARE MODEL IN A NORTH CAROLINA PUBLIC
HEALTH SETTING

by

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Dedication

This project is dedicated to the many people around the world impacted by viruses that do not yet have a cure; and the many frontline clinicians, especially those in resource limited settings, who care for the most challenging of patients. It is also dedicated to the researchers around the world working tirelessly to find cures.

Abstract

North Carolina (NC) has a prevalence of approximately 36,700 people living with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS). In 2016, there was an incidence rate of approximately 1,399 adults and adolescents who were newly diagnosed with HIV/AIDS. NC's HIV viral suppression rate was at 65%, well below the Joint United Nations Programme on HIV/AIDS (UNAIDS) goal of 90% suppression. The purpose of this project was to implement the University of California –San Francisco (UCSF) Rapid ART (Antiretroviral Therapy) Program Initiative for HIV Diagnoses (RAPID) model in a resource limited North Carolina public health setting. The UCSF RAPID care model implementation seeks to condense multiple steps for engagement in to care in to one visit resulting in same day linkage to care and initiation of ART, a process shown to improve retention in care and decrease time to viral suppression. Clinic staff included: NP (n=5), PA (n=1), MD (n=1), RN (n=2), MSW (n=2). Referrals came from STI clinics and outside referrals. Medication was obtained from starter/sample packs, patient assistance programs, HIV Medication Assistance Program (HMAP). Median days from diagnosis to first clinic visit was 17 and 86% of patients started ART at first clinic visit. RAPID implementation results shorter time from diagnosis to first clinic visit, decreasing the time to viral suppression. Implementation is feasible and sustainable.

Key words: ART, CD4, HIV, public health, rapid, resource limited, treatment, viral suppression

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Chapter One: Overview of the Problem of Interest

According to North Carolina (NC) Public Health (2016), 36,700 people live with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). An estimated 2,500 individuals were undiagnosed and unaware that they were infected. 1,399 adults and adolescents were newly diagnosed with HIV/AIDS, which was higher than the 2015 report. Of those living with HIV in NC, 80% were men who reported having sex with men (MSM), 53% were young men aged 13 to 29, while 5% acquired HIV through injection drug use (IVDU) (North Carolina Public Health, 2016). African American gay and bisexual men continue to be disproportionately affected by the epidemic, accounting for 39% of all new HIV diagnoses in 2015. According to AIDSVu (2018), in 2016, 45%, of all people in the United States diagnosed with HIV lived in the South. To put it another way, almost half of the United States population living with HIV lived in the South. In 2015, there were 3,617 people diagnosed with HIV and 132 new cases in North Carolina's Wake County (AIDSVu, 2018). In 2017, the Wake County Health Department received 193 new HIV patients (Wake County Human Services, 2017). Of those 193, 62 were newly diagnosed with HIV (Wake County Human Services, 2017). The purpose of this chapter is to describe the importance of beginning care as soon as possible after HIV diagnosis.

Furthermore, a National Institutes of Allergy and Infectious Disease (NIAID)-funded study, the Strategic Timing of AntiRetroviral Treatment (START), definitively answered the question of whether starting antiretroviral therapy (ART) sooner is better than delaying until CD4+ T-Cell count dropped (INSIGHT START Study Group, Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., et al. (2015). The answer favored starting ART as soon as possible (INSIGHT START Study Group et al., 2015). According to this NIAID study,

individuals who start earlier ART have a reduced risk for progressing to acquired immunodeficiency virus (AIDS) or acquiring comorbidities when compared to individuals who do wait until CD4+ T-cell counts drop. This NIAID study, along with data from additional studies (Cohen et al., 2011), indicated that HIV transmission to uninfected sexual partners was also reduced by the infected partner's treatment. In summary, clinical trials have demonstrated that individuals starting ART immediately after diagnosis had better health outcomes among patients and their partners than if patients delayed ART (INSIGHT START Study Group, Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., et al. 2015). Therefore, individuals should begin treatment as soon as possible to achieve viral suppression. Alternatively, individuals who present late to HIV specialist care are often ill, are less likely to respond to treatment when initiated and have high morbidity and mortality rates (Girardi, Sabin, & Monforte, 2007).

While some individuals living with HIV have insurance, many do not (Wake County Human Services, 2017). The uninsured depend on the HIV Medication Assistance Program (HMAP) as the payer source for ART. ADAP coverage services, processing steps, and approval times vary from state to state. In North Carolina, approval times range from 2 to 4 weeks, with up to a 4-week delay before starting ART (J. Lambert, personal communication, July 20, 2018). Even with insurance, prior authorizations may delay time until a patient can start ART. An additional problem is the delay between time of diagnosis until presentation to HIV care. Referral to an HIV specialist depends on when an appointment can be made, which could take days to months.

Significance of Clinical Problem

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has set a goal within their 90-90-90 campaign (Joint United Nations Programme on HIV/AIDS, 2013). That is: (1) 90% of all people living with HIV will know their HIV status by 2020, (2) 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy by 2020, (3) 90% of all people receiving antiretroviral therapy will have viral suppression by 2020. According to the *Health Equity and HIV in North Carolina* report (North Carolina Public Health, 2016), gay, bisexual, and other men who have sex with men (MSM) of color have the highest HIV rates in North Carolina. Once in treatment, however, disparity in care outcomes decreases. Viral suppression is one result of successful treatment care outcome. Although North Carolina has made progress, its viral suppression rate of 65% (North Carolina Public Health, 2016) falls below UNAIDS's 90% suppression rate goal.

Question Guiding Inquiry (PICO)

Is it possible to successfully implement the RAPID care model in a North Carolina public health setting?

Population.

The population included individuals who received a new diagnosis of HIV and were treatment naïve. The project site clinic provides care to individuals aged 18 years through end of life. The entirety of this age range was eligible for project inclusion.

Intervention.

The intervention consisted of (1) same day appointments for individuals newly diagnosed with HIV and (2) same day initiation of ART. Staff meetings incorporated explanations of the RAPID care model. Clinic staff included nurses, nurse practitioners, social workers,

phlebotomists, and disease intervention specialists. All staff in the sexually transmitted infection clinic (where HIV testing takes place) and field-testing sites must be alert for anyone with a positive test, and for those people to be escorted to the HIV clinic for immediate initiation of care. These two clinics are located within the same building and connected to each other.

Comparison.

The data from those individuals who participate in the project will be compared to pre-intervention data. Specifically, the time to first appointment and initiation of therapy will be evaluated. Prior to implementation, no standard was in place for same day appointments or treatment initiation.

Outcome.

The target outcome for this project was to implement same day ART therapy. This was measured by counting how many patients in the RAPID care group were diagnosed and seen for a first clinic visit on the same day. In addition, participants who were started on ART the same day as their first clinic visit was measured.

Summary

Although global goals have been set to diminish HIV's impact, HIV acquisition and transmission continues in North Carolina, with disproportionate occurrences in some groups. Prompt ART initiation in individuals with newly diagnosed HIV is important for individuals' health and for reducing HIV transmission. The RAPID care model, a model of same day testing and treating, has been demonstrated to be both safe and effective for individuals newly diagnosed with HIV (Pilcher et al., 2017).

Chapter Two: Review of the Literature

Literature Review Findings

This review included systematic reviews and meta-analyses, randomized controlled trials, cohort studies, and descriptive studies. Most of these studies involved discussion about intervention with ART. AIDS defining events and CD4 T cell count were often used as end markers for evaluation. In some publications, viral load was used to stratify the data. Of importance, there was no contemporary data indicating that a delay of ART initiation benefitted patients in the general population.

Methodology

Sampling strategies.

PubMed was the primary database used to find peer- reviewed articles for this project. These were accessed through East Carolina University's Laupus Library website. Key words used included: HIV antiretroviral therapy rapid start (67 results), HIV rapid start (141 results) and rapid ART start (51 results). Combined, these resulted in a total of 259 results with multiple types of articles, including randomized trials and meta-analyses. Reference lists from the initial articles were reviewed to expand the search. In particular, the protocol that this quality improvement project is guided by is based on Pilcher et al.'s (2017) publication. To obtain current local surveillance data and demographics, unpublished data was obtained from the Wake County Health Department (Wake County Human Services, 2017).

Evaluation criteria.

Forty-four articles were subsequently selected, with fifteen included in the final literature review after exclusion/inclusion criteria were applied. These 15 articles were selected after reading them individually for relevance to the project. In addition, two government websites,

one unpublished data source from a county health department were included. Only articles published within the last five years were included. Exceptions were made for articles of relevance or where more recent data was not available. Special attention was given to articles that compared outcomes between early initiation to late initiation of ART. Exclusions were made for articles that did not address either initiation of ART timing or the resulting outcomes. Articles were excluded that did not support the project. Relevance was defined as a publication's ability to provide meaningful contribution to the body of knowledge surrounding timing of ART initiation.

Literature Review

Importance of Early Treatment

Early ART initiation is imperative to improving morbidity and mortality in individuals diagnosed with HIV (Ananworanich et al., 2013; Grinsztejn et al., 2014; Zolopa et al., 2009). Ananworanich et al. (2013) included 47 participants in their study of early ART treatment. Early ART resulted in low reservoir size and absence of detectable HIV- integrated DNA in PMBC and memory CD4-T cells. This study indicated that early intervention resulted in the CD4 cells seeding the HIV reservoir. In a sub-Saharan Africa setting, Danel et al., (2015) found that immediately starting ART with isoniazid (IPT) preventive therapy resulted in lower rates of severe illness than if ART and IPT was deferred.

Grinsztejn et al. (2014) enrolled 1,763 HIV-1 infected serodiscordant couples, (a couple in which one individual is HIV positive and one individual is HIV negative,) and assigned them to either early or delayed antiretroviral treatment (at the time of their research the optimal time to initiate ART was still being evaluated in the scientific community). The study demonstrated that early initiation of ART delayed length of time to an AIDS event (examples including

tuberculosis and severe bacterial infections) and incidence of other outcomes including stage 2,3, and 4 HIV-1 and death.

Zolopa et al. (2009), studied differences between individuals randomized to either early ART given within 14 days of starting opportunistic infection (OI) treatment or deferred ART after OI treatment was completed. The group that received early ART encountered less AIDS progression/death or loss of virologic response when compared to participants who received deferred ART. De Cock and El-Sadr (2013) described that immunologic recovery will lag if ART is delayed and that uncontrolled HIV replication results in immune activation and inflammation.

Viral suppression has been found across multiple studies to reduce HIV transmission risk among serodiscordant couples (Cohen, et al., 2011; Grinsztejn et al., 2014). Grinsztejn et al. (2014) found that early ART treatment reduced HIV-1 transmission by 96%. The median age was 33, with half of the study participants being men. Their study included 1,763 couples that included a serodiscordant partner, with 886 assigned to the early treatment arm and 877 assigned to the delayed treatment group. Early ART started at study enrollment while delayed ART began after two consecutive CD4 counts at or below 250. Early ART treatment reduced transmission rates and extended time to first clinical event among treatment group versus delayed treatment group (Grinsztejn et al., 2014). Additionally, it was found that early ART resulted in an HIV transmission incident rate of 1.2 per 100 person years, which was calculated using the Kaplan-Meier method, across both early and delayed ART initiation (Cohen et al., 2011). The early therapy group showed an incidence rate of 0.3 per 100-person years (4 events) while the delayed therapy group had an incidence rate of 2.2 per 100-person years (35 events). The early ART initiation group demonstrated a reduction of HIV-1 related clinical events by 41% in comparison

to the delayed ART initiation group. This finding supports early treatment with ART for HIV-infected persons, even with high CD4 count, with the effect of reducing transmission rates and decreasing clinical events.

Jain et al. (2013) suggested that ART, begun within 6 months of infection with HIV, is associated with a lower T-cell (CD4) activation and smaller HIV reservoir size than if begun after 2 or more years. The researchers examined a cohort of HIV patients who either began ART early (<6 months after infection) or later (2 or more years after infection) and who maintained two or more years of viral suppression. Demographics were men with median ages from 33 to 38 whose primary HIV risk factor was having sex with other men. Early ART was associated with lower CD4 T-Cell activation than in later ART group (5.3% vs 7.5%; $P = 0.06$). Early ART was also associated with a 4.8 x lower DNA level than found in the later ART participants ($P=0.005$).

The Writing Committee for the CASCADE Collaboration (2011) conducted an observational study with 9,455 patients on the effect of delaying ART. Most participants were men who acquired HIV from having sex with other men. Median age at seroconversion was 30.3. When results were stratified by CD4 counts of 200-349, 350-599, and 500-799, ART initiation at a CD4 counts <500 was correlated with slower disease progression when compared to deferring ART start within a given month

Contemporary Models of Early Initiation

Pilcher et al. (2017) described the hurdles that complicate rapid initiation of HIV treatment, including structural barriers, patient attitudes and provider attitudes. They wrote that testing sites and care sites are often in different locations leading to delays up to weeks before initiating care. Obtaining health insurance benefits to pay for treatment further complicate

treatment initiation. When an appointment is made, factors take priority over ART initiation, such as initial labs, post-test counseling and education, management of housing or substance abuse. In addition, Pilcher et al. (2017) explained that some healthcare providers defer ART until patients prove they can adhere to treatment by attending multiple appointments.

To address these issues, a clinical health systems intervention was launched by the San Francisco General Hospital HIV clinic, RAPID (Rapid ART Program for Individuals with an HIV Diagnosis). The aim of RAPID was to simplify ART initiation for individuals newly diagnosed with HIV by starting ART on the same day referred for care (Pilcher et al., 2017). Of 39 eligible patients who were managed on the RAPID protocol, 37 were started on ART within 24 hours. Minor toxicities were observed in only 2 (5.1%) from the intervention group in comparison to none in the non-intervention group. Additional studies have also reported that laboratory marker toxicities are low for both early and delayed ART start groups (Cohen, et al., 2011). Pilcher et al. (2017) also demonstrated that the time to virologic suppression (<200 HIV RNA/mL) was significantly faster (median 1.8 months) for those participants enrolled on the intervention arm versus those treated with previous recommendations for universal ART (4.3 months). Support that immediate ART initiation vs delayed initiation decreases time to viral suppression has been demonstrated across other studies as well (Lodi, et al., 2015; Pilcher et al., 2017).

Transmission Rates

There are many benefits to a RAPID approach. Among these are a reduction in HIV reservoir size (the small persistent collection of latently infected cells in individuals infected with HIV) in acute infection settings (Ananworanich, et al., 2013; Jain, et al. 2013), decreased complications, and elimination of transmission during the acute phase (Bellan, Dushoff, Galvani,

& Meyers, 2015; Brenner et al., 2011; Hollingsworth, Pilcher, Hecht, Deeks, & Fraser, 2015; Pilcher et al., 2007; Wawer et al., 2005). From an epidemiologic standpoint, factors that may be driving and contributing to the transmission of HIV in urban settings include being in a large cluster group which include >10 sexual partners versus those in smaller clusters with fewer sexual partners (Brenner et al., 2011). However, it should be noted that Brenner et al. (2011) have shown that small cluster groups also report higher anal-insertive risk activities than their large-cluster counterparts.

Bellan et al. (2015) estimated based on viral load-infectivity that the chance of transmission at peak viral load during acute phase is approximately nine times greater than at the chronic phase set point. The researchers also estimated the median transmission rate between partners to be 12 (4.6 – 30) per 100 person-years with the heterogeneity in transmission to be 2 (1.2 – 2.8). According to their report, “2” corresponds to individuals at the 97.5% quantile (highest risk) having a 50-fold greater transmission rate than the median. Wawer et al. (2005) wrote that HIV transmission per coital act were highest during early-stage infection. This observation is an indication for early ART treatment. Early treatment with ART is also associated with reduced morbidity and mortality in individuals with HIV infection (Pilcher et al., 2007).

Limitations of Literature Review Process

Because confirmation of early treatment importance and evidence of efficacy of the RAPID model emerged in the last 5 years, there are limited peer-reviewed journal articles. There is also a still small, but growing, number of rapid start protocols that are being used across the United States, each varying to accommodate the needs of the respective locations that they were created for (Pilcher et al. 2017; Florida Division of Health, 2018). Because rapid start

protocols are historically developed to accommodate specific healthcare systems, they may potentially not be effectively implemented in their entirety in a given health care setting.

Financial resources are also a noticeable factor that may reveal variation between the health system a protocol was intended for and an outside system.

Discussion

Conclusion of findings.

The literature suggests that ART initiation should happen as soon as possible after diagnosis of HIV (INSIGHT START Study Group, Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., et al. (2015). Additionally, rapid ART start is both feasible and tenable (Pilcher et al., 2017). It could potentially be a worthwhile endeavor for clinics in public health settings to implement test and treat protocols. The RAPID care model is a recent model indicating safety and efficacy (Pilcher et al., 2017). Given these literature findings, the RAPID care model was chosen for this project.

Advantages and disadvantages of findings.

Early initiation of ART is the preferred approach versus a delay in initiation. Early implementation helps individuals living with HIV to maintain a better quality of health and avoid potential illnesses. The RAPID protocol developed by Pilcher et al. (2017) specifically showed that rapid ART initiation achieves faster time to viral suppression and better adherence outcomes. Specifically, Pilcher et al.'s (2017) design which included a red-carpet process for engagement in to care and initiation of ART will be an advantage. Their model also includes providing transportation for the first visit which provides additional advantage for patients who are transportation limited. These factors will also be advantageous to the affected population,

which is primarily comprised of men who have sex with men. However, heterosexual couples, too, will benefit, as well as a diverse age range, from 18 years of age and up.

Disadvantages described in the literature appear to be more theoretical based on perceived structural barriers, barriers that more so describe limitations to executing a rapid start (financial resources, access to medication, and policies/procedures) versus a disadvantage for the patient. International studies, in particular those in sub Saharan Africa, provide environments that are unique and varied in comparison to the study locations in the United States. Resource limited locations, in general, present with their own unique challenges that are not often faced in the United States, including financial limitations, limited access to the latest technology innovations, and a less developed and established healthcare infrastructure. However, most studies involving exploration of transmissibility, viral suppression, and negative outcomes are generalizable to the United States. The majority of studies reviewed did provide inferential statistics, which does allow them to be generalized to the general public.

Utilization of findings in practice.

Implementation of the RAPID protocol may vary and look different from clinic to clinic. However, the model has demonstrated efficacy. Thus, clinics should attempt to find a process that may be operationalized in their practice setting. Given the resource differences between the line by line specifics of the RAPID care model and what is available at the project implementation site, the project site will adapt, staying as true as possible to the RAPID care model for the promotion of fast, efficient, and effective engagement in to care.

Summary

Recent findings are reshaping the landscape of HIV care. Antiretroviral therapy should be offered immediately to all individuals with HIV. A rapid start approach for those with newly

diagnosed or untreated HIV has been shown to improve morbidity and mortality. Achieving a rapid start program in the public health setting is possible, sustainable, and in line with current best practices.

Chapter Three: Theory and Concept Model for Evidence-based Practice

Theoretical Framework

Described as having written one of the most intellectually challenging pieces on American politics, Kingdon sought to explore the process that occurs prior to decision making (Quirk, 1986). According to Quirk (1986), Kingdon sought to understand why some items make it on to agendas while others do not. In Kingdon's *Alternatives and Public Policies*, as reported by Mooney & Evans (2007), he illustrated a model of agenda setting that includes three separate streams, each operating relatively independently from the other. To reach this discovery, Kingdon modified a garbage can model which described a policy agenda as being constructed from three process streams, these streams being primarily concerned with problems, policies, and politics (Quirk, 1986). In contrast to the garbage can model, Kingdon's views of decision making suggest that the three streams were overall independent, each following its own course and responding to its own influences (Quirk, 1986).

Within the first stream, a person becomes occupied with, and aware of, the problem, partly through the monitoring of systematic indicators (Kingdon & Thurber, 1984). However, they can also emerge with less organization and more unpredictability in events like disasters or crises. Kingdon suggests that subtleties of this process will have a powerful effect primarily when the item takes a problem and provides additional support for problems' perceptions that already exist (Kingdon & Thurber, 1984).

According to Quirk (1986), Kingdon's second stream involves the process of forming and providing revisions to a particular policy proposal. Within this process, ideas are invented, researched, and amended mostly by experts working in loosely organized policy communities (Kingdon & Thurber, 1984). These ideas may be offered several times before they are ever

taken seriously; a time referred to as softening-up (Kingdon & Thurber, 1984). Most of the ideas will die out during this time; the ideas that meet criteria for survival will be the ones that succeed (Kingdon & Thurber, 1984). According to Kingdon (1995), some of the criteria are defined and enforced by the policy community itself; some of these criteria may include *technical feasibility*, *value acceptability*, and *anticipation of future constraints*. *Technical feasibility* describes whether the idea is fully worked out and whether there is a practical and attainable implementation plan (Kingdon, 1995). *Value acceptability* is primarily concerned with an item's compatibility within the values of the policy community. *Anticipation of future constraints* is characterized by the notion that the idea must be viewed to have potential, to have reasonable budgetary costs and have prospects of approval from politicians, and the public (Kingdon, 1995). Lastly, there is a political stream comprised of other categories such as public mood, pressure group campaigns, election results, partisan or ideological distributions, and changes of administration or legislative turnover. Any one of these may levy large effects on the agenda (Hodge, 2006).

Application to practice change.

The first stream (recognition of the problem) is characterized by awareness that there is a need to start individuals living with HIV on ART as soon as possible, although this may be a slow process. The second stream is represented by healthcare organizations recognizing a need and changing their healthcare policies, as well as most notably Pilcher's et al.'s (2017) RAPID model previously described. The culture shift occurring where providers are becoming more amenable to the RAPID model represents the third stream. In addition, pharmaceutical companies are responding to pressure to provide means for patients to quickly access ART. At

the present time, each of these streams are converging, providing an optimal time to engage and initiate a rapid ART start program in a NC public health setting.

Concept Analysis

The concept introduced in this quality improvement project is the RAPID start protocol. Developed by Pilcher et al. (2017), its aim is to start individuals on ART as soon as possible after a new diagnosis of HIV. Their work has shown rapid ART starts to be both save and effective. The ART component of the protocol references the HIV treatment aspect of the protocol. Furthermore, it illustrates that this protocol is specifically designed for individuals diagnosed with HIV. Going a step further, it is applied to individuals who are newly diagnosed (by rapid or confirmatory HIV test) and treatment naïve, meaning that the individual had never previously taken ART.

EBP Change Theory

Adoption of innovation has been studied as a concept for over 30 years. One of the most popular models is Rogers 2002, *Diffusion of Innovations* (Shahin, 2006). Diffusion of innovations has been applied to a broad spectrum of occupations (Dooley, 1999; Stuart, 2002). Rogers uses the terms “technology” and “innovation” interchangeably. Rogers defines *technology* as a “design for instrumental action that reduces the uncertainty in the cause-effect relationships involved in achieving a desired outcome (Rogers, 2003, p. 13). Rogers (2003) also describes innovation as an idea or concept that is perceived as new by the individual who will adopt it. Even if the idea or concept was invented long ago, if it is new to the individual, it may be received as innovation.

According to Rogers, “*adoption* is a full use of an innovation as the best course of action available” (Rogers, 2002, p. 177). Lastly, *diffusion* is defined by Rogers as “the process in

which an innovation is communicated through certain channels over time among the members of a social system” (Rogers, 2003, p. 5).

Rogers’ Four Concepts

These four concepts, innovation, communication channels, time, and social system, form the diffusion of innovations theory (Rogers, 2003; Sahin, 2006). Rogers (2003) also suggested that uncertainty may be a barrier to the adoption of innovations. To mitigate uncertainty, he advises that individuals be informed about advantages and disadvantages. Consequences may also be classified into the following categories: desirable versus undesirable (functional or dysfunctional), direct versus indirect (immediate result or result of the immediate result) and anticipated versus unanticipated (recognized and intended or not) (Sahin, 2006).

Rogers (2003,) described communication as a “process in which participants create and share information with one another in order to reach a mutual understanding” (p.5), with this communication occurring through channels between different sources (Rogers, 2003; Sahin, 2006). Rogers (2003) elaborated that diffusion is a special kind of communication that includes: an innovation, two individuals or other units of adoption, and a communication channel. Rogers also describes diffusion as a social process characterized by interpersonal communication relationships (Rogers, 2003). Thus, interpersonal channels are powerful in creating or changing strong individual attitudes.

Rogers’ 5 Steps

Rogers’ (2003) innovation-decision process involves five steps: 1) knowledge, 2) persuasion, 3) decision, 4) implementation and 5) confirmation. As a routine, these steps usually occur sequentially (Rogers, 2003; Sahin, 2006). It is within the knowledge stage where an individual learns about an innovation’s existence. During the knowledge step, questions of

“what?”, “how?”, and “why?” are critical (Rogers, 2003). It is also during this step that the individual is seeking to learn how and why an innovation works (Rogers, 2003).

The persuasion stage occurs when an individual develops a negative or positive attitude about an innovation (Rogers, 2003). Because this stage is more affective, with more emphasis on personal feelings, individuals deal more sensitively with the innovation during the persuasion stage (Sahin, 2006), this means that there is more room for personal feelings to be involved during the persuasion stage. Social influence about the proposed innovation may also impact an individual’s beliefs about an innovation (Rogers, 2003).

It is during the decision stage in which the individual makes a choice to adopt or reject the innovation (Rogers, 2003). When an innovation has a partial trial basis, the usual outcome is that the innovation is adopted quicker (Rogers, 2003). While adoption is hoped for, rejection is possible at any stage of the process (Rogers, 2003). Rejection may manifest as either active or passive rejection. In active rejection the individual tries an innovation but later decides against adopting it. When an individual does not even think about adopting the innovation, passive rejection occurs (Rogers, 2003).

When an innovation has been put into practice, the implementation stage has been reached (Rogers, 2003). At this stage, uncertainties about the outcomes of the innovation may still be a problem. During this stage the individual implementing the innovation may benefit from support from change agents or other individuals to mitigate uncertainties within an organization about the potential consequences (Rogers, 2003). Once the innovation has reached this stage it also transitions away from being an innovation since its distinctive newness wears off (Rogers, 2003). As time goes on and users adopt the innovation, reinvention may occur, which is a process by which the innovation is changed or modified (Rogers, 2003).

The confirmation stage is characterized by the innovation-decision having already been made (Rogers, 2003). During this stage the individual looks for support for their decision. If exposed to conflicting messages within an organization, the decision to adopt the innovation may even be reversed (Rogers, 2003). Because the individual will seek supportive messages that confirm their decision, attitudes become a more crucial factor. The following support for the adoption of the innovation can impact future adoption or discontinuance (Sahin, 2006).

Evidence Based Practice Model Application

Each of Roger's five steps will be utilized in the successful implementation of this quality improvement project. The knowledge stage was characterized by multiple individual and group meetings which answered the questions of how, what, and why. To help reduce uncertainty, the staff was informed about advantages and disadvantages. Staff involved was given a chance to ask questions and understand the basic constructs of the RAPID care model. As staff wrestled through their feelings of support or skepticism about the project they journeyed through the stage of persuasion. As staff eventually accepted and supported the project they moved through the decision stage. Once the project has been put in to place the innovation stage will be manifested. The confirmation stage will commence once the project is implemented and support is sought after to affirm the success of the project.

Summary

Considering that the RAPID ART initiation model is relatively new to NC public health settings, adoption of the model must occur. A persuasion stage must happen prior to project implementation. During this phase, the clinic staff and stakeholders will need to be persuaded about importance of prompt ART initiation. The decision stage will be critical, in that successful implementation will depend upon whether the involved individuals have committed to support

the RAPID model. Once implementation occurs, it will provide an innovative, new concept within the NC public health system, allowing prompt ART initiation. Whether the innovation was successfully implemented will be determined during the confirmation stage.

Chapter Four: Pre-implementation Planning

The following chapters describe the pre-implementation planning process for quality improvement project in a public health setting in the southeastern United States.

Project Purpose

The purpose of this quality improvement project was to implement the RAPID Care Model in a southern state public health setting. It aimed to provide a same day appointment for individuals who were newly diagnosed with HIV. In addition, same day ART initiation was offered and provided when clinically appropriate. The primary idea was to simplify the multiple steps individuals routinely encountered in their journey to care and treatment and create an easy on ramp to engagement in care.

Project Management

Organizational readiness for change

The Health Department was ready for this organizational change. Historical structural barriers, such as availability of an ART supply in clinic and cost of medication, had been overcome and no longer presented the resistance to rapid care that they once did. Specifically, pharmaceutical companies had been working with the Health Department to provide starter packs of ART, which were accessed by the patient on the same day as diagnosis. In addition, administrative, clinical, and support staff were educated, had taken interest in the rapid start process and were aware of the public health benefit, including improved retention in to care and faster time to viral suppression. Meetings were scheduled with upper administration to help coordinate all stakeholders and staff to provide patients quick entry to care after diagnosis. Administrative staff had demonstrated enthusiasm in backing the implementation of the RAPID care model.

Inter-professional collaboration.

A multidisciplinary approach was necessary for the RAPID Care model to be successfully implemented and was highlighted by the need for successful transitions and hand-offs. When diagnosed at the initial clinic, a nurse or nurse practitioner would personally walk the patient over to the second clinic and assisted the patient with accessing immediate care. When a patient was diagnosed at a site outside of the Health Department, a Disease Intervention Specialist would offer the patient a same day appointment and, if accepted by the patient, would notify the clinic to schedule an immediate same-day appointment. A social worker visited with the patient and communicated with clinical staff relevant findings to augment care. Case managers were called upon to assist in coordinating transportation for patients to their first clinic appointment. Laboratory phlebotomists provided services for obtaining and processing labs.

Risk management assessment.

The organization did have the necessary skills in-house, including clinical expertise, social work, case management, and lab processing. The budget allowed for successful implementation of this quality improvement project. An application was submitted for grant funding to provide transportation and additional case management services; at the time of this document the result of the application had not yet been determined. Consistent with previous publications, the health department benefited from increased patient retention in to care. No new equipment or technology was required. The team involved was able to provide expert leadership and clinical expertise in the implementation of this quality improvement project.

The project did not incur additional costs for the operations of the clinic. Through Ryan White federal funding, the clinic did have funds to help newly diagnosed patients receive care.

A drawback of the project included additional time burden on staff. No part of this project needed to be outsourced.

Organizational approval process.

Multiple individual and group meetings were held to get leaders on board. This included casual informal, impromptu meetings, formal gatherings to brainstorm, and boardroom presentations to present and answer questions. Special attention was given to include direct stakeholders who both directly and indirectly benefited. Each meeting garnered additional support and enthusiasm for the potential of the project. Primarily the latest evidence-based information was presented during each interaction. The capstone of the organization approval process was approval by the organization's research review board. Prior to approval, a meeting with department administrative personnel was held and there was unanimous favor for implementing this quality improvement project. Approval was granted via verbal affirmation (Appendix B).

Information technology.

Information technology utilized in this project included electronic resources, including electronic medical records, and computer software. Hardware included computers for data processing and phones for communication.

Cost Analysis of Materials Needed for Project

Antiretroviral therapy costs vary, although the average cost of a first line regimen is \$3,500 for a 30-day supply. Because samples of product were supplied for starter packs, as well as use of patient assistance programs, there was no charge incurred to the clinic. The cost of transportation was estimated to be at \$2,880 to provide transportation to and from the first two clinic visits for 30 people. A grant was submitted to help cover the cost of transportation. An

additional \$19,094 was requested in the form of a grant to provide support for additional for a peer educator, as well as \$654 for the peer educator to drive to a patient if needed. Ultimately, funds were not obtained from this grant and external funding sources were not utilized as part of this project.

Plans for Institutional Review Board Approval

The UW-Madison QI/Program Evaluation Self-Certification Tool was used to assess the need for IRB approval, which per East Carolina University was categorized as a quality improvement project and not human research. In result, full IRB review was not needed. This information (Appendix C) was then submitted to the Wake County Human Services research review board for their verbal approval.

Plan for Project Evaluation

Demographics.

In order to describe the participants involved in this quality improvement project, the following demographic data was collected via the data collection tool (Appendix D): age, gender, and race. Age was reported as a mean, mode, and standard deviation. Race and gender were statistically processed as nominal data. This data was presented in figures, tables, and graphs as appropriate.

Outcome measurement.

The first outcome measurement was the number of patients who were seen for clinical care the same day that they receive a HIV diagnosis. In terms of the project, this was the component of the RAPID protocol that aimed to streamline entry in to care. The second outcome measured was the number of patients who were started on ART the same day as their first appointment. This too was a component of the RAPID protocol that aimed to initiate patients on ART as soon as possible.

Evaluation tool.

For the purpose of measuring primary outcomes, specific information was collected. This included whether an appointment was scheduled and kept for the same day as diagnosis, whether ART was started on the same day as the first clinic visit, and the mode of referral to the HIV clinic. The data collection tool used to collect this data is noted in Appendix D.

Data analysis.

Measures of central tendency were used to analyze demographic and project specific data when appropriate. Generally, descriptive statistics were used for analyzing the project data. SPSS served as the statistical software for analyzing the data collected.

Data management.

Microsoft Excel served as the spreadsheet on which data was entered and managed. The spreadsheet was housed on a computer that was password protected and secured in a locked office. Data was kept for 6 months after project closure or expiration of IRB approval. Hard copy data was destroyed via shredding. Digital copies were completely deleted from the storage computer.

Summary

In summary, demographic, as well as project specific data were collected. A project data collection tool was used to collect the data. The data was described using measures of central tendency and descriptive statistics. Data was managed with an Excel spreadsheet that was securely stored to protect patient information. Excel and SPSS served as the software for running statistical analysis.

Chapter Five: Implementation Process

The implementation process was characterized by professional collaboration across multiple disciplines, including nursing, medical, allied health, and administrative contributors. The setting included a public health setting with participants who were newly diagnosed with HIV.

Setting

A public health center located in a southeastern state served as the project setting. Specifically, the clinic was located within a public health center that serves and cares for individuals diagnosed with HIV, including provision of primary care. Five nurse practitioners, two nurses, one physician assistant, and one physician staffed the clinic. In addition, the clinic had on staff two social workers, one referral coordinator, two patient advocates, two therapists, and one psychiatrist. The clinic had eight exam rooms. It had an adjacent phlebotomy lab, which was a short walk from the clinic, where in-house HIV testing occurred. The public health center was located on major bus lines and next door to a major hospital.

Participants

Participants were included from a population of new and newly diagnosed HIV cases registered for care in a southeastern state public health setting. Excluded were participants who were not new and newly diagnosed, and those individuals who do not wish to engage in care.

Recruitment

Participation in this quality improvement project was offered to everyone who presented to the clinic as new and newly diagnosed with HIV. Because this was a quality improvement project, no informed consent was needed. However, participants did have the benefits of rapid ART start explained to them as part of standard counseling and education during their first visit.

They also had alternative options explained so that they were able to make an informed decision about their health care. Alternative options included deferral or transfer of care and deferral of ART initiation.

Implementation

Process implementation occurred for 12 weeks. Any time a positive HIV test resulted at the southeastern state public health clinic, or at any other ambulatory site within the county, participants were offered a same day visit at the clinic. Following the algorithm of the RAPID care model (Appendix E), participants met with a clinician who initiated care and, when appropriate, started them on ART the same day. During the course of the initial visit they had labs drawn, including complete blood count, chemistry panel, human leukocyte antigen (HLA) B5701, hepatitis panel, lymphocyte/CD4 count, viral load, HIV 1 and 2 differentiation, HIV genotype, HSV 1 and 2 antibody, hemoglobin A1C, glucose-6-phosphate-dehydrogenase (G6PD), toxoplasma antibody, cytomegalovirus antibody, lipid panel, RPR, chlamydia/gonorrhea nucleic acid amplification testing. These labs were part of the current standard of practice therefore obtaining them did not incur any additional costs. Finally, they were seen by a staff representative to complete registration at the clinic and process financial paperwork (Appendices E and F).

Plan Variation

The RAPID care model in its original form provided for transportation to and from the first clinic visit. At the time of this documentation a grant request had been submitted to provide for transportation, however it had not yet been approved at the time of study implementation. The RAPID care model also indicated that a social worker would meet with the patient at the first visit. Due to scheduling availability, and newness of the concept, a social worker was not

always available during the first visit. Lastly, given the resource-limited environment of the project implementation site, funding sources were inherently different and unique from previous locations of protocol implementation.

Summary

In summary, successful implementation of this project in a public health setting involved thorough planning with multiple stakeholders to achieve successful roll out. Interprofessional collaboration was be paramount in optimizing each step of the process. It also required staying within the boundaries of the project parameters to recruit and enroll the targeted patient population.

Chapter Six: Evaluation of the Practice Change Initiative

The project was implemented for 12 weeks in a North Carolina public health setting. Individuals who had a diagnosis of HIV, had never been seen by an HIV specialist, and were treatment naïve were included in the project.

Participant Demographics

During the time of project implementation, there were a total of seven cases eligible for inclusion. Of these seven, six identified as male and one identified as female. Three identified as Hispanic/Latino, two identified as Black/African American, and two identified as White/Caucasian. The median age was 30.1 years with a range from 22 to 38 years of age.

Intended Outcomes

The intended outcomes were to 1) link individuals who were newly diagnosed with HIV to care as quickly as possible, ideally being seen for a first clinic appointment on the same day as diagnosis and 2) start individuals on ART as soon as possible (when clinically appropriate) after diagnosis.

Findings

The majority of patients were seen in an HIV clinic < 90 days after diagnosis. One case was seen the same day of diagnosis, three cases were seen within 30 days of diagnosis, two cases were seen within 31 to 90 days of diagnosis, and one case was seen >90 days after diagnosis (Appendix G). Of the seven eligible patients, six were started on ART the same day as their first clinic appointment. One case was started 4077 days after their day of diagnosis. Five were referred through Under One Roof (a case management service), one was a direct internal referral from the STI clinic, and one was a direct referral from an outside clinic.

Summary

In summary, the majority of cases were seen for a first appointment within 30 days of diagnosis, while the majority of cases were started on ART the same day as their first appointment. Most cases were referred to the clinic from an internal case management service. .

Chapter Seven: Implications for Nursing Practice

The implementation of this project demonstrates that nurses are well positioned to be at the forefront of changing healthcare practice for the good of individuals who are newly diagnosed with HIV. The DNP essentials guide the development and implementation of the DNP project by creating a framework and roadmap for students throughout the evolution of the project (Moran, Burson, & Conrad, 2016). Furthermore, the DNP essentials help distinguish doctoral level education from master's level education (Moran, Burson, & Conrad, 2016). In addition, they help ensure that the DNP projects are safe, effective, patient centered, timely, efficient, and equitable (Moran, Burson, & Conrad, 2016).

Practice Implications

Essential I: Scientific underpinnings for practice.

This essential is defined by analyzing and using information to develop practice, while also translating research to improve practice. Implementation of this project used evidence based practice to improve practice outcomes. The implication is that use of evidence-based practice is an integral part of the healthcare delivery system. Literature was reviewed using a search engine and this led to the selection of a protocol and development of an implementation plan, subsequently allowing for translation of current evidence in to clinical practice and application. .

Essential II: Organization and systems leadership for quality improvement and systems thinking.

Advocacy for improved quality, access, and cost of healthcare contribute to the definition of this essential. Multiple meetings were held before and during the implementation of this project to obtain support from key stakeholders. The implication is that advocacy may be an important consideration when preparing to implement a quality improvement project. Specific to

this project, standard operating procedures were developed in collaboration with the organization to successfully implement the project. The protocol selected for implementation was validated and published in a peer reviewed journal. An approach of beneficence was used to minimize ethical risk. The project was also implemented in a way that did not incur any additional cost to the organization. Rather, additionally needed resources came in the additional time needed for investment by staff.

Essential III: Clinical scholarship and analytical methods for EBP.

Critical analysis of the literature, application of knowledge, and implementation of strategy contribute to this definition. Implementation of this project was modeled after the previously validated UCSF RAPID Start Protocol. The implication is that a literature review is an essential component of a quality improvement project. The literature review overwhelmingly revealed that starting on ART is better than a delay with regard to health and outcomes. It also revealed that a rapid start of ART resulted in better retention in to care and decreased time to viral suppression. An exploration of the data and evidence showed that the viral suppression rate for North Carolina is below the target goal of 90% set by UNAIDS. This information helped develop the project and ensure successful implementation.

Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare.

As a component, this essential is defined by the evaluation of systems of care using health information technologies. An electronic medical record was used to manage patient health records. The implication is that an understanding of healthcare technology is important for effectively implementing a quality improvement project. This is important because use of an EMR could allow for compiling and aggregating data. As well, it would also allow for the

evaluation of data. Once available for evaluation, data can be available for comparison and for determining if specific goals and targets are being achieved. Use of an EMR also allows for longitudinal tracking of data to closely watch change over time.

Essential V: Healthcare policy for advocacy in healthcare.

Leadership, organizational influence, education, and advocacy define this essential. The implementation of this project challenged the status quo and presumed standard for expected length of time until a first clinic visit and initiation of ART. It resulted in new standard operating procedures being written and new expectations for clinical staff. Stakeholders were also educated regarding policies and best practices. The implication is that doctoral prepared nurses will be well positioned to lead within the healthcare system. Specifically, it dually served as a demonstration project to show other under resourced clinics across the region and nation that they, too, can implement rapid start protocols. This would also enable them to improve retention in care and decrease time to viral suppression, helping them achieve national goals for HIV care.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes.

This is defined by the use of effective collaboration and communication, as well as interprofessional consultation. Multiple agencies were utilized in the implementation of this project. Contributors included social workers, internal clinics, and outside clinics. The implication is that interprofessional collaboration is a key component of quality improvement within the healthcare system. Healthcare systems commonly rely on multiple disciplines and field specialties to effectively deliver quality care to their patients; interprofessional collaboration is imperative to this quality delivery. Effective interprofessional collaboration allowed for diverse skill sets to holistically contribute to the project. With each expert making professional contributions to the

project, it allowed for optimal care of the patient. Leadership skills were conveyed through advocacy, promotion, and implementation of the rapid care model.

Essential VII: Clinical prevention and population health for improving the nation's health.

This essential is defined by evaluating and implementing change strategies of models of health care delivery to improve quality and address diversity. Faster linkage to care and rapid initiation of ART contributes to the United Nations 90-90-90 goal. They also reduce incidence of negative outcomes for individuals living with HIV. The implication is that evaluation and implementation of change strategies are important for quality improvement. A specific goal of Healthy People 2020 is that any individual diagnosed with HIV would have a clinic visit with an HIV specialist within 30 day of diagnosis. The implementation of a rapid start protocol is one potential option for helping clinics achieve national goals and objectives, including Healthy People 2020 goals.

Essential VIII: Advanced nursing practice.

This essential is defined by demonstration of advanced clinical judgment and systematic thoughts to improve patient outcomes. The implementation of nurse practitioner-led care contributed to the clinical care that individuals included in this project received. Through this project's implementation, new standard operation procedures were developed that updated older practices and aligned clinical care more in line with current evidence based practice. The implication is that advanced practice nurses are an integral part of advancement within the healthcare delivery system. Critical thinking was used to implement and adapt a protocol developed in California and apply it to an under resourced public health clinic in North Carolina.

Guidance and mentorship came in the form of educating front line clinical staff on the importance of rapid starts.

Summary

In summary, this project implementation met each of the DNP essentials. Components included scientific underpinnings, organizational leadership, clinical scholarship, information technology, advocacy, collaboration, clinical prevention, and advanced nursing practice. Through the project's implementation and meeting each of the DNP essentials, implications resulted that highlighted the importance of advanced practice nurses within the healthcare delivery system.

Chapter Eight: Final Conclusions

The implementation of this project highlights two separate, but closely related factors in the cascade towards viral suppression of HIV: 1) linkage to care and 2) initiation of ART. More importantly, it demonstrates that it is possible to implement a rapid ART start protocol in a resource limited setting.

Significance of Findings

The clinical significance of this project is the demonstration that it is possible to implement in a resource limited setting the steps proven to improve linkage to care, retention in care, and time until viral suppression. The implication for the patients is better adherence to care and fewer missed visits. Once viral suppression is achieved, HIV cannot be transmitted, leading to a reduced transmission rate. Once suppressed, negative outcomes are reduced, and patient health is improved.

Project Strength and Limitations

The ability to start an individual on ART the same day as their first clinic visit was found to be a strength. This was facilitated by the sample packs of ART that pharmaceutical companies provided to the clinic. Except for one person, all cases were started on ART the same day as diagnosis. The one individual who was not started on ART the same day as their first visit was delayed due to a mutual conversation with their PCP who chose to approach their initiation the way ART starts have historically been handled. Follow up appointments were appropriately scheduled and kept by the patients. In addition, the multi-disciplined team that was currently in place was found to be a strength, as it streamlined communication amongst the multiple disciplines and minimized training and education needed to implement the project.

The acceptance of the implementation by staff varied throughout the course of the project. In the beginning there were some clinicians who were completely on board. There were also some clinicians who were not completely on board, but became fully accepting of the implementation as things progressed. As implementation resulted in better understanding of what successful implementation looked like, all staff were on board and accepting of the concept. In result, what was both a liability and strength evolved into a strength.

The inability to quickly link individuals to care after their diagnosis was found to be a limitation. The UCSF protocol utilizes an on-call paging system to link newly diagnosed individuals to care, as well as taxi vouchers to transport people to their visit. Unfortunately, these resources were not available for the implementation of this project, and perhaps contributed to some patients not being seen for a first clinic visit on the same day of diagnosis. Additionally, the city in which the project was implemented for this project lacked the same robust public transportation system that San Francisco has historically had.

This project may be leveraged both locally and nationally and has already been implemented in California and Florida prior to this site implementation. Private clinics may have an easier time implementing a rapid care model given more patients with insurance, however implementation of the rapid care model in a resource limited public health setting is a novel concept. New technology developments include new ART regimens that pharmaceutical companies were actively trying to achieve FDA approval for, and subsequent use in the population and use for rapid starts.

Project Benefits

The primary benefit of this quality improvement project was the improvement of clinical practice. It challenged the status quo and antiquated practices that some clinicians in the clinic

were slow to give up and demonstrated to them that rapid starts are tenable. It also benefited the patients by providing them with the best chance, based on current evidence, of quickly becoming virally suppressed and optimizing their health.

Recommendations for Practice

Future recommendations for practice include increased efforts to improve linkage to care. While this clinic demonstrated that rapid initiation of ART is possible at a resource limited NC public health setting, linkage to care proved to be a challenge. Additional time is needed to work with ancillary staff and team members to reduce the time between diagnosis and first clinic visit. An increased sample size will add robustness to the data. In addition, as time progresses, it will be possible to correlate those who were rapidly started on ART with time to viral suppression and reveal whether results are consistent with other clinics that have implemented rapid start models. The progression of time will also allow for proper evaluation of the project's sustainability. Whether the implementation of rapid start is still going on at the clinic down the road will be an empirical measure of the project's sustainability. Plans are also in place to submit an abstract to the Conference on Retroviruses and Opportunistic Infections. Further research to be explored includes assessing provider perceptions and feelings about their experiences with the implementation of rapid start models.

Final Summary

The implementation of this quality improvement project was birthed from the observation of a need within a resource limited NC public health system. Within the field of HIV, research and clinical care often coupled together in real time. Much of the ground gained in clinical care is the direct result of grass roots advocacy just a few decades ago at a time when HIV did not yet have name. Today, with the advances that have been made and relative ease of medication

management, it is hard to imagine that options for treatment were as limited as they once were. The rapid start models are one more step on the path towards advancement and an eventual cure. While resourced and resource limited clinics may feel that they are operating on different planes, a rapid start model is one thing that any clinic, no matter the operating budget, can implement to advance clinical care for their patients. In time, more advances will be made. Clinicians engaged in HIV care should incorporate continual advancement into the fabric of their practice.

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Internal Medicine, 171(17), 1560-1569. doi:10.1001/archinternmed.2011.401 [doi]

Zolopa, A., Andersen, J., Komarow, L., Sanne, I., Sanchez, A., Hogg, E., ... & ACTG A5164

study team. (2009). Early antiretroviral therapy reduces AIDS progression/death in

individuals with acute opportunistic infections: A multicenter randomized strategy trial.

PloS One, 4(5), e5575. doi:10.1371/journal.pone.0005575 [doi]

Appendix A

Literature Review Matrix

Evidence Matrix
Evidence as the Basis for Practice Change

This evidence table-matrix is provided as a tool to assist students in tracking relevant articles that contain key data/evidence found when conducting their literature review. The tool will assist students in recording key articles that are relevant to their evidence-based practice (EBP) change project, more importantly, reflecting data/evidence to support the “intervention” they identified. The tool should be used continuously as students search the literature. Once an article has been selected that clearly contains data/evidence to support the intervention and is being considered for inclusion in the final literature review, complete the following exercise:

- 1) List each article that contains relevant data/evidence in the table below. Evidence that will be included in the final literature review paper.
- 2) Across from each article, identify the level of evidence and the “key data/evidence/outcomes/findings” associated with that article. Actual data should be listed as shown in example below.
- 3) Identify what you have concluded from the data/evidence and the article’s overall findings.
- 4) Indicate how you will use the article and evidence when planning the practice change project.

Important note: The evidence matrix should only include articles and data/evidence that support the project.

Remember, if there is little or no evidence published on how to improve practice specific to the problem, then another problem must be identified. It is not possible to plan an EBP change project if little or no evidence exists.

Also, when planning the project, each part of the plan must be based on quality evidence.

In NURS 8269, you will be required to submit your evidence table-matrix (reflecting work completed to date) as part of your final course paper submission. Your review of the literature will be an ongoing process, therefore we do not expect this to be an all-inclusive table, but a representation of the evidence you have found to date that is in clear support of your proposed intervention. In addition, this evidence table-matrix will assist you in writing the findings section of the literature review (see guidelines for the Project Paper). ***This evidence table-matrix also needs to be submitted in subsequent DNP Project Courses as an appendix document with the drafts and final submission of the project paper.*** Students can add rows to the table as needed.

Levels of Evidence

Level 1 - Systematic review & meta-analysis of randomized controlled trials; clinical guidelines based on systematic reviews or meta-analyses

Level 2 - One or more randomized controlled trials

Level 3 - Controlled trial (no randomization)

Level 4 - Case-control or cohort study

Level 5 - Systematic review of descriptive & qualitative studies

Level 6 - Single descriptive or qualitative study

Level 7 - Expert opinion

Source: Melnyk, B.M. & Fineout-Overholt, E. (2011). *Evidence-based practice in nursing and healthcare: A guide to best practice*. Philadelphia: Lippincott, Williams & Wilkins. Retrieved from

<http://guides.lib.umich.edu/c.php?g=282802&p=1888246>

Student:	Course :	Faculty Lead:	Date:	Project:
Article (APA Citation)	Level of Evidence	Data/Evidence Findings	Conclusion	Use of Evidence in EBP Project Plan (Include your evaluation,

	(I to VII)			strengths/limitations, and relevance)
Author (XXXX) study on the topic of fall reduction in dementia patients in a long-term care facility	Level VI	Initiating hourly rounds during the hours of 4P-6A was shown to decrease resident falls by 50%, decrease LOS by 20% and increase patient satisfaction by 25%.	Hourly rounding between the hours of 4P and 6A was effective in decreasing falls, LOS and increasing satisfaction	Include hourly rounding between the hours of 4P and 6A in the fall prevention practice change.
AnanworanichJ, Vandergeeten C, Chomchey N, et al. (2013). Early ART intervention restricts the seeding of the HIV reservoir in long-lived central memory CD4+ T cells [abstract #47]; Program and abstracts of the 20th Conference on Retroviruses and Opportunistic Infections (Atlanta, GA)	Level I	ART during early HIV infection significantly restricts the HIV reservoirs compared with later treatment.	Early ART has a greater impact in limiting the HIV reservoirs than later treatment.	Adds to the body of knowledge that early ART implementation is important, especially on the physiologic level.
Bellan, S. E., Dushoff, J., Galvani, A. P., & Meyers, L. A. (2015). Reassessment of HIV-1 acute phase infectivity: Accounting for heterogeneity and study design with simulated cohorts. <i>PLoS Medicine</i> , 12(3), e1001801. doi:10.1371/journal.pmed.1001801 [doi]	Level IV.	Use of Bayesian modeling to re-estimate duration and relative infectivity of the acute phase.	Many, many statistics were found, however their result showed that 10 mo survey intervals cannot distinguish b/w shorter, highly infectious, and less infectious acute phase b/c of long intervals.	Statistics in this report estimated transmission rates for various phases.
Brenner, B. G., Roger, M., Stephens, D., Moisi, D., Hardy, I., Weinberg, J., et al. (2011). Transmission clustering drives the onward spread of the HIV epidemic among men who have sex with men in quebec. <i>The Journal of Infectious Diseases</i> , 204(7), 1115-1119. doi:10.1093/infdis/jir468 [doi]	Level IV	Large clusters disproportionately had increase in infection.	Tailored prevention approaches are needed across social networks and risk behaviors.	Simply reinforces the importance of treatment.
Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. <i>N Engl J Med</i> . 2011	Level II	Participants receiving early therapy had fewer	Early ART intervention reduced rates of sexual	Reinforces importance of early ART.

Aug 11;365(6):493–505. Epub 2011 Jul 18. PMID: 21767103		treatment end points	transmission of HIV and clinical events	
De Cock, K. M., & El-Sadr, W. M. (2013). When to start ART in africa--an urgent research priority. <i>The New England Journal of Medicine</i> , 368(10), 886-889. doi:10.1056/NEJMp1300458 [doi]	Level I	Over time, since the 90's the building body of knowledge has shown that early ART improves outcomes. The authors believe that additional clinical trials are needed	Early initiation of ART improves outcomes	Early ART initiation is imperative.
Girardi, E., Sabin, C. A., & Monforte, A. D. (2007). Late diagnosis of HIV infection: Epidemiological features, consequences and strategies to encourage earlier testing. <i>Journal of Acquired Immune Deficiency Syndromes</i> (1999), 46 Suppl 1, S3-8. doi:10.1097/01.qai.0000286597.57066.2b [doi]	Level I	Late presenters to care tend to be those who perceive low risk.	Strategies that promote early testing may help individuals gain awareness of their HIV status, helping to control the spread of the epidemic	Testing and treatment are part of a comprehensive approach to controlling the HIV epidemic.
Grinsztejn, B., Hosseinipour, M. C., Ribaud, H. J., Swindells, S., Eron, J., Chen, Y. Q., et al. (2014). Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: Results from the phase 3 HPTN 052 randomised controlled trial. <i>The Lancet Infectious Diseases</i> , 14(4), 281-290. doi:10.1016/S1473-3099(13)70692-3 [doi]	Level II	40 vs 61 AIDS events in participants in early vs delayed ART group. 498 (early) vs 585 (late) primary/secondary outcomes in early vs delayed.	Early initiation of ART delayed time to AIDS events and decreased the incidence of primary/secondary outcomes	Reinforces that early ART initiation is imperative.
HIV.gov (2018, June 1). A timeline of HIV and AIDS. Retrived from https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline	Level I	This is a timeline that relies of multiple sources to provide a historical meta analysis	HIV persists	Continued efforts are needed to stop the HIV epidemic.
Hollingsworth, T. D., Pilcher, C. D., Hecht, F. M., Deeks, S. G., & Fraser, C. (2015). High transmissibility during early HIV infection among men who have sex with men-san francisco, california. <i>The Journal of Infectious Diseases</i> , 211(11), 1757-1760. doi:10.1093/infdis/jiu831 [doi]	Level IV	Early infection was estimated to be a highly infectious period. Evidence that transmissibility is not the same across the years.	High infectivity in population-level transmission is limited by the short duration of this stage of infection but will be increased by high rates of partner change.	Early ART is important in reducing the highly infectious period that happens early in acquisition.

INSIGHT START Study Group, Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., et al. (2015). Initiation of antiretroviral therapy in early asymptomatic HIV infection. <i>The New England Journal of Medicine</i> , 373(9), 795-807. doi:10.1056/NEJMoal506816 [doi]	Level II	Endpoint occurred in 1.8% of early ART initiation vs 4.1% in the deferred initiation groups	ART initiation in adults with CD4 over 500 provides benefit over waiting until a decline	Early ART initiation is imperative.
Jain, V., Hartogensis, W., Bacchetti, P., Hunt, P. W., Hatano, H., Sinclair, E., et al. (2013). Antiretroviral therapy initiated within 6 months of HIV infection is associated with lower T-cell activation and smaller HIV reservoir size. <i>The Journal of Infectious Diseases</i> , 208(8), 1202-1211. doi:10.1093/infdis/jit311 [doi]	Level II	Early ART predicted lower CD4 activation than with later ART (5.3 vs 7.5%, $P=.6$) and lower cell-associated RNA levels $P=0.35$	ART initiation < 6 months after infection is associated with lower levels of t cell activation and smaller HIV DNA/RNA reservoir size during long term therapy.	Early ART is better than delaying.
Joint United Nations Programme on HIV/AIDS. (2013). 90-90-90: An ambitious treatment target to help end the AIDS epidemic. Retrieved from http://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf National Institute of Allergy and Infectious Disease (2015). Starting antiretroviral treatment early improves outcomes for HIV-Infected Individuals: NIH-funded trial results likely will impact global treatment guidelines. Retrieved from https://www.niaid.nih.gov/news-events/starting-antiretroviral-treatment-early-improves-outcomes-hiv-infected-individuals	Level I	UNAIDS treatment target plans to end the AIDS epidemic. Status report.	Goal: 90 % will be aware of status, 90% will be on ART, 90% will be virally suppressed	The challenge of defeating HIV is a global effort.
North Carolina Public Health (2016). Health equity and HIV in North Carolina, 2016: Gay, bisexual, and other men who report sex with men (MSM) of color have the highest estimated rates of HIV in North Carolina.	Level I	Successful treatment leads to viral suppression; once suppressed, HIV cannot be transmitted to others.	North Carolina is on track to meet and exceed the National HIV/AIDS Strategy viral suppression goal	North Carolina is making progress in the effort to achieve targets. 8
Pilcher, C. D., Joaki, G., Hoffman, I. F., Martinson, F. E., Mapanje, C., Stewart, P. W., et al. (2007). Amplified transmission of HIV-1: Comparison of HIV-1 concentrations in semen and blood during acute and chronic infection. <i>AIDS (London, England)</i> , 21(13), 1723-1730. doi:10.1097/QAD.0b013e3281532c82 [doi]	Level IV	39 of 39 patients began ART w/in 24 hours.	Treatment for HIV can happen on the same day of diagnosis w/out impacting safety or acceptability of ART	Initiating ART on the same day of diagnosis is tenable.
Samji, H., Cescon, A., Hogg, R. S., Modur, S. P., Althoff, K. N., Buchacz, K., et al. (2013). Closing the gap: Increases in life	Level IV	Life expectancy was lower for individuals with a	A 20 yo HIV-positive adult on ART in the	Being on ART is imperative to the health

expectancy among treated HIV-positive individuals in the United States and Canada. PloS One, 8(12), e81355. doi:10.1371/journal.pone.0081355 [doi]		history of injection drug use, non-whites, and in patients with baseline CD4 counts <350 cells/mm3.	U.S. or Canada is expected to live into their early 70 s, near that of the general population.	maintenance of individuals living with HIV.
TEMPRANO ANRS 12136 Study Group. Danel C, Moh R, Gabillard D, et al. (2015). A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa. N Engl J Med. 2015 Aug 27;373(9):808–822. Epub 2015 Jul 20. PubMed PMID: 26193126	Level II	Risk of death or sever HIV-related illness was lower with early ART than with deferred ART	Immediate ART and 6 months of isoniazid led to lower rates of severe illness than deferred ART or not IPT	Early ART is imperative.
Wake County Human Services. (2017, December 31). Clinic a hip program 2017 cqi information. Unpublished internal document.	Level VI	Description/presentation of new patients presenting to Wake County Health Dept	Wake County is continuing to see new and newly diagnosed patients.	Wake county is a location that could benefit from the test/treat approach.
Wawer, M. J., Gray, R. H., Sewankambo, N. K., Serwadda, D., Li, X., Laeyendecker, O., et al. (2005). Rates of HIV-1 transmission per coital act, by stage of HIV-1 infection, in rakai, uganda. The Journal of Infectious Diseases, 191(9), 1403-1409. doi:JID33445 [pii]	Level IV	Rate of HIV transmission per coital act was 0.0083/coital act w/in 2.5 months after seroconversion of the index partner.	Rate of HIV transmission per coital act was highest during early stage infection.	Early ART implementation may help reduce some forms of early stage infection.
Zolopa, A., Andersen, J., Powderly, W., Sanchez, A., Sanne, I., Suckow, C., et al. (2009). Early antiretroviral therapy reduces AIDS progression/death in individuals with acute opportunistic infections: A multicenter randomized strategy trial. PloS One, 4(5), e5575. doi:10.1371/journal.pone.0005575 [doi]	Level I	AIDS progress/death was seen in 14% (early) vs 24% (late)	Early ART initiation resulted in less AIDS progression/death with no increase in adverse events or loss of virologic response compared to delayed	Early ART initiation is imperative.

Appendix B

WCHS Approval

[WCHS Approval removed to protect identifying information]

Appendix C

WCHS Application

[WCHS Application removed to protect identifying information]

Appendix D

Project Data Collection Tool

DNP Project Data Collection Tool

1. Age? _____

2. Gender? _____

3. Race/Ethnicity? (circle one below)

Asian – Black/African American – White – Hispanic/Latino-
American Indian/Alaska Native – Native Hawaiian/Pacific Islander –
Mixed Race - Other

4. Was an appointment made and kept for the same day that a reactive HIV test was resulted?

(circle one) Yes OR No

5. Was antiretroviral therapy (ART) started on the same day as the initial appointment?

(circle one) Yes OR No

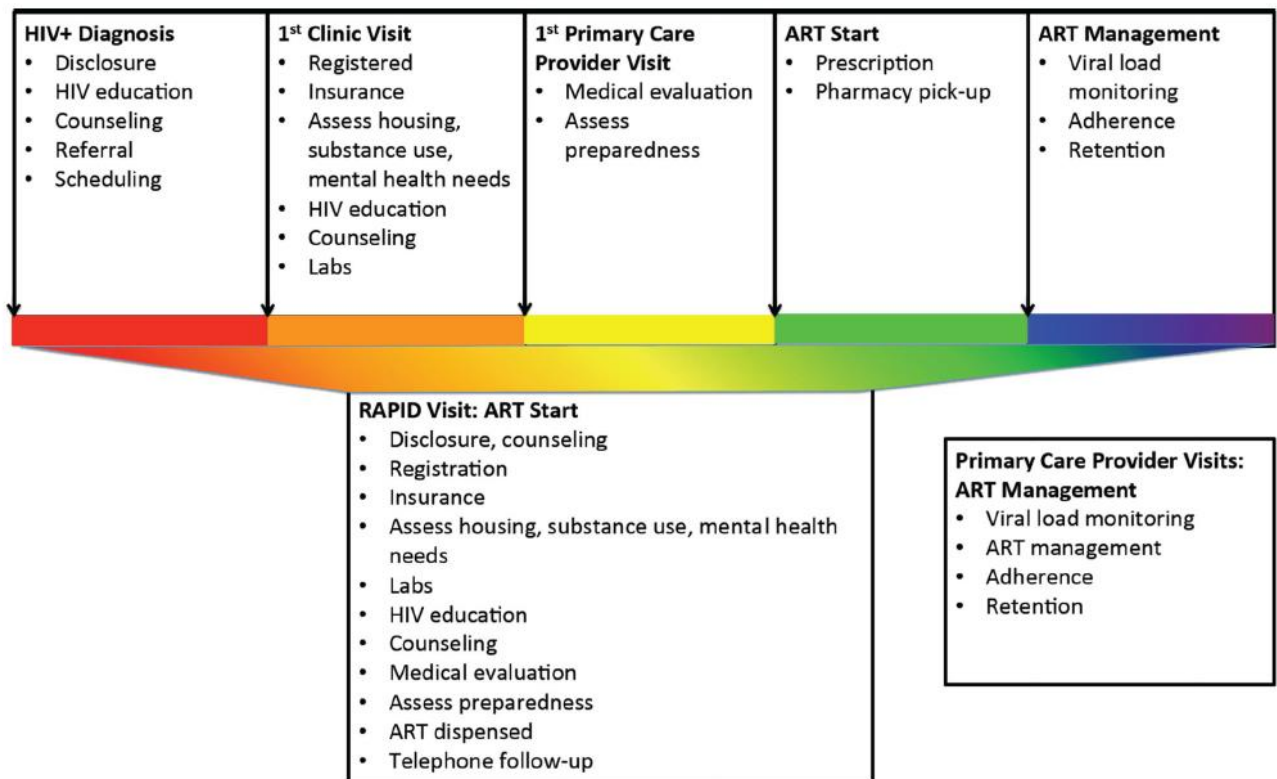
6. What was the mode of scheduling the initial appointment?

(circle one below)
Disease Intervention Specialist (DIS) –
Direct Referral from within Health Department-
Self-Scheduled – Hospital – Outside Clinic – Other

This data collection tool will be used to collect information that will help describe the population being studied within a North Carolina public health setting. This information will be kept and stored on an Excel spreadsheet for analysis that will describe the participants of the quality improvement project. The tool may be presented in poster, paper, or electronic format.

Appendix E

UCSF Rapid Care Model



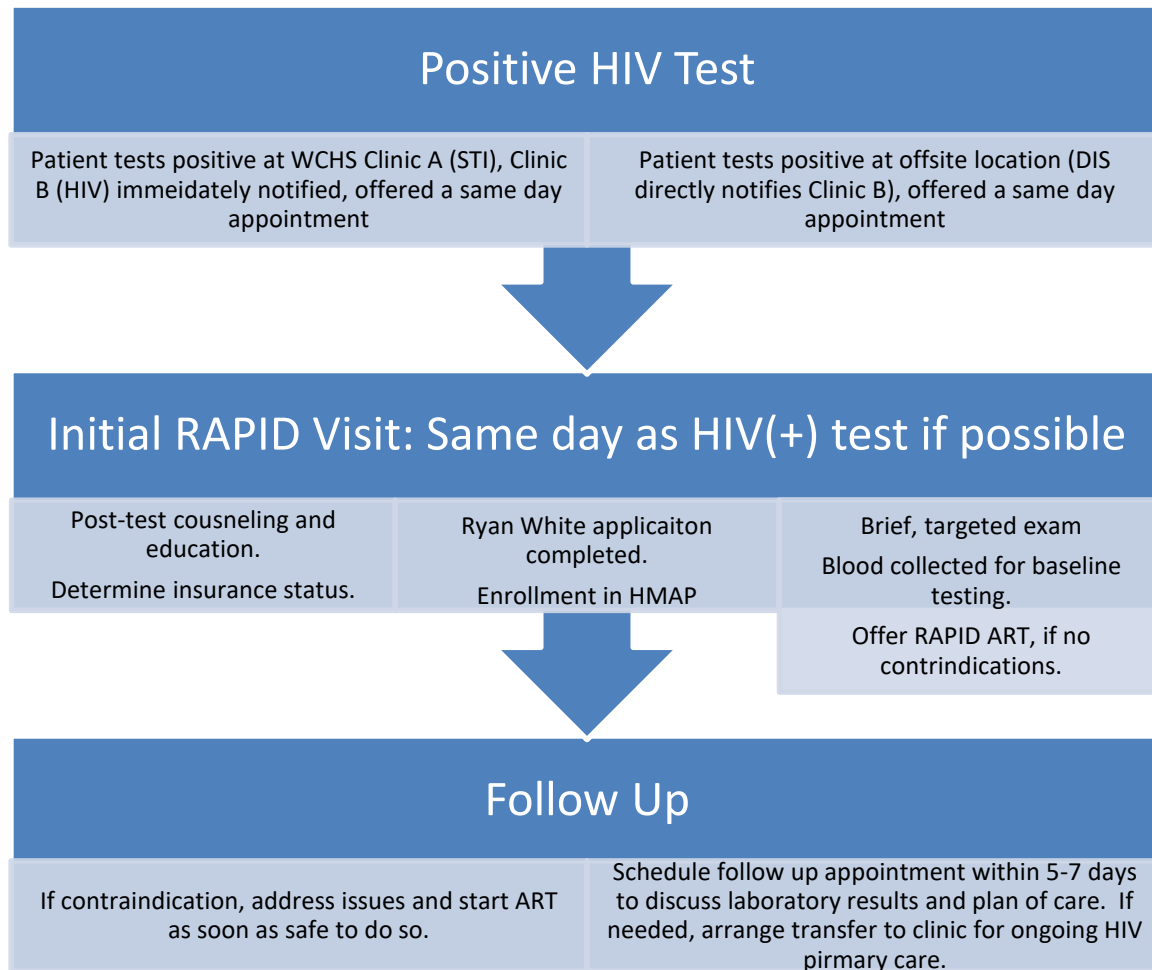
Pilcher, C. D., Ospina-Norvell, C., Dasgupta, A., Jones, D., Hartogensis, W., Torres, S., et al.

(2017). The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. *Journal of Acquired Immune Deficiency Syndromes* (1999), 74(1), 44-51. doi:10.1097/QAI.0000000000001134 [doi]

This flow sheet describes the consolidation of events from current practices in to the rapid care model and will be used as an illustration to help clinical staff and those involved in direct patient care and contact better understand how the rapid care delivery model compares with the current process that they are generally accustomed to. It may be presented in poster, paper, or electronic format.

Appendix F

NC RAPID Protocol Patient Flow Chart



This flow sheet describes the process for rapidly engaging a newly HIV-diagnosed patient in to clinical care in a North Carolina public health setting. It will be used to present the concept to clinical providers and those who may have direct patient contact. It may be used in poster, paper, or electronic format.

Appendix G

Days Until First Appointment

